

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

NATURAL RESOURCES DEFENSE
COUNCIL, INC.,

Plaintiff,

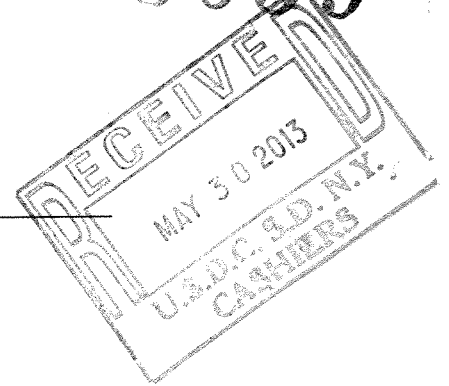
v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION; and CENTER FOR
VETERINARY MEDICINE,

Defendants.

13 CV 3659

13 CIV _____
ECF Case



COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Defendants United States Food and Drug Administration (FDA) and Center for Veterinary Medicine (CVM) violated the Freedom of Information Act (FOIA), 5 U.S.C. § 552, by failing to timely disclose responsive records requested by plaintiff Natural Resources Defense Council, Inc. (NRDC) concerning the volume of antibiotics used in livestock and the presence of antibiotic-resistant bacteria in meats.

2. Approximately 80 percent of all antibiotics sold in the United States today are used in livestock production. The vast majority of these drugs are administered flock- or herdwide at low doses for nontherapeutic purposes, such as promoting animal growth and preventing diseases that tend to occur when animals are kept in cramped and unsanitary conditions.

3. The proliferation of antibiotics in animal feed and water is linked to a growing and dangerous trend of antibiotic resistance. Research has shown that the use of antibiotics in livestock production leads to the development of antibiotic-resistant bacteria that can be

transferred from animals to people through direct contact, environmental exposure, and the consumption and handling of contaminated meat and poultry products. People who contract antibiotic-resistant infections are more likely to have longer hospital stays and may be more likely to die as a result of the infection.

4. FDA is responsible for regulating the use of antibiotics in livestock under the Food, Drug, and Cosmetic Act. FDA has tasked CVM with evaluating the safety of animal drugs, including livestock antibiotics.

5. FDA and CVM conduct surveillance of antibiotic-resistant bacteria in retail meats as part of the National Antimicrobial Resistance Monitoring System. FDA and CVM also collect data about the annual volume of antibiotics used in livestock production under the Animal Drug User Fee Act.

6. NRDC filed a FOIA request with FDA and CVM on November 2, 2012, seeking (1) records containing any data or analysis associated with the National Antimicrobial Resistance Monitoring System Retail Meat Reports other than the published reports and (2) all records that assess or speculate upon the volume of antibiotics used annually in food-producing animals, broken out by various parameters. FDA acknowledged receipt of the request on November 9, 2012. FDA and CVM's response was due, at the latest, on December 24, 2012.

7. To date, FDA and CVM have failed to produce any documents in response to NRDC's request or to provide NRDC with a final determination as to whether they will comply with the request.

8. NRDC requests a declaration that FDA and CVM have violated FOIA by failing to produce responsive records by the statutory deadline and an injunction ordering that FDA and CVM immediately disclose to NRDC all non-exempt, responsive records.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B).

10. Venue is proper in this district pursuant to 5 U.S.C. § 552(a)(4)(B) because plaintiff NRDC resides and has its principal place of business in this judicial district.

THE PARTIES

11. Plaintiff NRDC is a national not-for-profit environmental and public health membership organization with 1.4 million members and activists. NRDC engages in research, public education, and litigation to improve the regulation of harmful substances in food, drugs, and consumer products.

12. Defendant FDA is a federal agency within the meaning of FOIA. *See* 5 U.S.C. § 551(1). FDA has possession or control of the records that NRDC seeks in this action.

13. Defendant CVM is a federal agency within the meaning of FOIA. *See id.* CVM has possession or control of the records that NRDC seeks in this action.

STATUTORY AND REGULATORY FRAMEWORK

14. FOIA requires agencies of the federal government, upon request, to make records “promptly available” to the public. 5 U.S.C. § 552(a)(3)(A).

15. An agency must determine whether to comply with a FOIA request within twenty business days and “shall immediately notify the person making such request of such determination and the reasons therefor.” *Id.* § 552(a)(6)(A)(i).

16. The twenty-day deadline for an agency to determine whether to comply with a FOIA request begins on the earlier of (1) the date the request is first received by the “appropriate component of the agency” or (2) ten days after the request is first received by “any component of

the agency that is designated in the agency's regulations . . . to receive [FOIA] requests”
Id. § 552(a)(6)(A)(ii).

17. If an agency does not respond to a FOIA request by the statutory deadline, the requestor is deemed to have exhausted administrative remedies and may immediately pursue judicial review. *Id.* §§ 552(a)(6)(C)(i), 552(a)(4)(B).

FACTS

18. FDA and CVM conduct surveillance and collect data about antimicrobial resistance of foodborne bacteria in humans, retail meat, and animals through the National Antimicrobial Resistance Monitoring System (NARMS). A summary of the data on retail meats is published in the NARMS Retail Meat Reports each year. However, the disaggregated data upon which these reports are based are not publicly available.

19. FDA and CVM also collect antimicrobial use data pursuant to the Animal Drug User Fee Act. 21 U.S.C. § 360b. Under this act, sponsors of new animal drugs containing antimicrobial active ingredients must annually report to the Secretary of Health and Human Services the amount of each antimicrobial active ingredient by container size, strength, and dosage form; by quantities distributed domestically and quantities exported; and by dosage form, including a listing of the target animals, indications, and production classes that are specified on the approved label of the product. *Id.* § 360b(l)(3)(A), (B). However, FDA and CVM make only basic summaries of this information available to the public.

20. On November 2, 2012, NRDC sent a FOIA request to FDA and CVM, via fax and overnight courier service, to the address designated on FDA's website and in the Code of Federal Regulations for receiving such requests. *See* 21 C.F.R. § 20.40(a).

21. NRDC's FOIA request sought data regarding antimicrobial resistance of foodborne bacteria. Specifically, NRDC requested records containing antimicrobial resistance

data or analysis associated with the NARMS Retail Meat Reports published by FDA and CVM for the years 2002 through 2012, including but not limited to (1) all available information about each meat sample collected by FDA and CVM; (2) the sample identification number; (3) the date that the sample was taken; (4) the date of laboratory analysis; (5) the location where the sample was found (city, state, zip code); (6) the type of sample (chicken breast, ground turkey, etc.); (7) the brand name and type of product (fresh, frozen, processed, etc.); (8) a full list of each species of bacteria found to be present on each sample; and (9) the antimicrobial susceptibility for each class of antimicrobials tested (for each bacterium). The request did not seek the published reports.

22. NRDC's FOIA request additionally sought data regarding the use of antibiotics in livestock collected pursuant to the Animal Drug User Fee Act or other authority. Specifically, NRDC requested all records that estimate, assess, or speculate upon the volume of antibiotics used, sold, or distributed for use in animal agriculture (1) for different uses or indications (e.g., growth promotion/feed efficiency, disease prevention, treatment of sick animals, etc.); (2) broken out by route of administration and dosage form; (3) for use in each food-producing animal species (poultry, swine, and beef, broken out in greater detail, if available); and (4) for use in each food-producing species by use or indication (e.g., volume sold for disease prevention in poultry in 2010). NRDC's request further sought records that estimate, assess, or speculate upon any trends in the use of antibiotics in food-producing animals between 2000 and 2012.

23. NRDC also sought a fee waiver.

24. FDA confirmed receipt of NRDC's FOIA request by letter dated November 9, 2012.

25. FDA granted NRDC's request for a fee waiver by letter dated November 20, 2012.

26. FDA and CVM's response was due, at the latest, on December 24, 2012. *See* 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. § 20.41(b).

27. On January 11, 2013, NRDC contacted FDA and CVM via email and telephone about the status of the request and asked that the documents be made available on a rolling basis.

28. On February 13, 2013, NRDC contacted FDA and CVM via email to ask for an update about the progress of the response to the request.

29. On March 14, 2013, NRDC once again contacted FDA and CVM via email about the status of the request.

30. To date, neither FDA nor CVM has produced any documents in response to NRDC's FOIA request.

31. To date, neither FDA nor CVM has provided NRDC with a final determination of whether it will comply with NRDC's FOIA request.

CLAIM FOR RELIEF

32. NRDC incorporates by reference all preceding paragraphs.

33. FDA and CVM have violated their statutory duty under FOIA, 5 U.S.C. § 552(a), to release non-exempt, responsive records to NRDC.

34. NRDC has a statutory right under FOIA to immediately obtain all requested records that are not exempt from disclosure under FOIA.

REQUEST FOR RELIEF

WHEREFORE, NRDC requests that this Court enter judgment against FDA and CVM as follows:

- A. Declaring that FDA and CVM have violated FOIA by failing to produce non-exempt records responsive to NRDC's FOIA request by the statutory deadline;
- B. Ordering that FDA and CVM disclose all responsive, non-exempt records to NRDC at no cost within fifteen days;
- C. Awarding NRDC its reasonable costs and attorneys' fees; and
- D. Granting such other and further relief as the Court deems just and proper.

Dated: New York, New York
May 30, 2013

Respectfully submitted,

Nancy S Marks

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